Adapted Kaizen: Multi-Organizational Complex Process Redesign for Adapting Clinical Guidelines for the Digital Age

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Abstract

The need for a method to examine complex, multidisciplinary processes involving many diverse organizations initially led multiple US federal agencies to adopt the traditional Kaizen, a Lean process improvement method typically used within a single organization, to encompass multiple organizations each with its own leadership and priorities. First, the Centers for Medicare and Medicaid Services and the Office of the National Coordinator for Health Information Technology adapted Kaizen to federal agency processes for the development of electronic clinical quality measures. Later, the Centers for Disease Control and Prevention (CDC) further modified this adapted Kaizen during its Adapting Clinical Guidelines for the Digital Age (ACG) initiative, which aimed to improve the broader scope of guideline development and implementation. This is a methods article to document the adapted Kaizen method for future use in similar complex processes, illustrating how to apply the adapted Kaizen through CDC's ACG initiative and showing the reach achieved by using the adapted Kaizen method. The adapted Kaizen includes pre-Kaizen planning, a Kaizen event, and post-Kaizen implementation that accommodate multidisciplinary and multi-organizational participation. ACG included 5 workgroups that each developed products to support their respective scope: Guideline Creation, Informatics Framework, Translation and Implementation, Communication and Dissemination, and Evaluation. Despite challenges gathering diverse perspectives and balancing the competing priorities of multiple organizations, the ACG participants produced interrelated standards, processes, and tools—further described in separate publications—that programs and partners have leveraged. Use of a siloed approach may not have supported the development and dissemination of these products.

Keywords:

Kaizen, process improvement, guideline development and implementation, lean, agile, multidisciplinary

Introduction

One of the most perplexing cross-disciplinary challenges in health care is the lag time from evidence generation to application in patient care. Balas and Boren

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determined that the average time gap is about 17 years,[1] though a recent article highlights the complexities in accurately representing the true time gap.[2] While certain parts of this process have shown some implementation improvements (eg, use of tools such as clinical decision support [CDS]),[3–6] finding the root causes of the lag time requires a multidisciplinary, multi-organizational approach. This led the US Centers for Disease Control and Prevention (CDC) to start an initiative called "Adapting Clinical Guidelines for the Digital Age" (ACG).[7] ACG aimed to improve a complex process that involves multiple organizations and disciplines and chose an adapted Kaizen approach to identify and confront the issues causing the long lag times from evidence generation to implementation in patient care. Focus areas included: (1) guideline creation, (2) informatics, (3) translation and implementation, (4) communication and dissemination, and (5) evaluation. CDC kicked off the ACG initiative with a Kaizen event in February 2018, followed by a multi-year implementation. This article centers on the adapted Kaizen method, using the ACG initiative to illustrate how the method can be applied. The ACG initiative, including the products of each of its workgroups, is summarized in a separate article.[8]

Background

The US federal government has a long history of investing in innovation that changes entire industries, despite its slowness to modernize.[9,10] In 2009, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act.[11,12] This set the ambitious goal for the US Department of Health and Human Services (HHS) to upgrade the US health care system from a paper-based to an interoperable, electronic system. The HITECH Act required a major update to the processes and IT systems of most of the health care industry, which have long been identified as inefficient, hard to learn, and resistant to change.[13–16]

In 2012, through sponsorship of the HHS Office of the Chief Technology Officer and with direct support from the HHS secretary, an entrepreneurs-in-residence (EIR) program was established. The EIR program matched internal HHS teams wanting to tackle a critical problem with skilled innovators who were looking to make a meaningful impact.[17–20] HHS recruited 2 external Lean experts to work with the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health IT (ONC) to adapt industry methods (eg, Agile software development, Lean manufacturing, and Human-Centered Design) to government processes, beginning with electronic clinical quality measures (eCQMs). Lean, a proven method for business process improvement, first started in 1951 with the Toyota Production System[21] and focused on improving areas by removing waste in the system within the control of the organization. Lean includes Kaizen, a Japanese philosophy that means continuous improvement, like the common quality improvement method of Plan-Do-Study-Act,[22] and involves managers and workers alike when applied to business processes.[23] The initial CMS and ONC Kaizen included participants from federal government agencies and organizations under contract with CMS or ONC. The CMS and ONC approach resulted in significant improvements, including reducing eCQM development cycle time by 3 years, decreasing defects by 95%, and increasing satisfaction for all who were impacted throughout the process.[20] These types and magnitude of improvement were on par with the kind of change CDC wanted with ACG, though the more complex nature of the guideline development and implementation process would require additional adaptations beyond those made by CMS and ONC.

The initial Kaizens led by CMS and ONC were part of a wave of participatory government initiatives, including innovation challenges,[24] Human-Centered Design projects,[25] and Agile software transformations.[26] CDC, CMS, ONC, National Institutes of Health, Veterans Health Administration, and various other federal and nongovernmental organizations later applied what they learned by participating in those initial Kaizen events, though the adaptation from business processes to government-like processes was never formally published. This article describes how CDC applied adapted Kaizen in the ACG initiative and documents the method for future use.

Methods

The adapted Kaizen method was selected to guide participants through the process of adapting clinical guidelines for use in digital systems and includes pre-Kaizen planning, the Kaizen event, and post-Kaizen event implementation. The key differentiators for the adapted Kaizen versus a traditional Kaizen for health care are summarized in Table 1 and include (1) multidisciplinary representation and involvement of participants from multiple organizations each with its

Table 1. Key Differentiators Between Traditional and Adapted Kaizen.

Traditional Kaizen	Adapted Kaizen	Adaptation
Single organization	Multiple organizations	Impacted groups from different organizations were represented throughout the Kaizen process (except pre-Kaizen, which was only within the sponsoring organization)
Narrow scope (single process)	Broad scope (complex process with interrelated sub-processes)	Mapping of the current states (of each sub-process) reconciled the processes of multiple organizations into a single representation
		Every workgroup included each type of expertise required in the complex process[a]
		Information sharing sessions were added to the Kaizen event to help bridge understanding among different disciplines that may not have previously interacted[a]
Changes impact single organization	Changes impact many organizations	Proposed future states (of each sub-process) incorporated the perspectives and priorities of multiple organizations
		Developed interrelated and complementary products to further help remove siloes[a]
Co-located participants	Dispersed participants (eg, different geographic locations)	Provided a virtual option for partial participation in Kaizen event[a]
N/A	Regular project champion meetings during post-Kaizen implementation	Project champions (ie, workgroup leads) updated each other on progress, successes, and challenges and helped each other to resolve challenges
		All initiative participants invited to project champion meetings to contribute (eg, problem-solving, providing insights from their respective disciplines or organizations)[a]

[a]Additional adaptations in CDC's model.

own leadership and priorities, (2) a scope that includes a complex cross-functional process with multiple interrelated sub-processes, and (3) application to constructs that impact many groups (eg, national policy, clinical guidelines). The ACG initiative's lead and the primary facilitator for CDC's Kaizen event participated in the CMS and ONC Kaizens and then brought the model to CDC. The adapted Kaizen was then further modified to accommodate a complex, multidisciplinary, multi-organizational process—guideline development and implementation—that is partially outside of CDC's control and therefore harder to influence and achieve process improvement. Accommodations to help bridge the experience gap across the different types of subject matter and technical expertise that are integral to guideline development and implementation and a virtual option for partial participation by remote participants were additional adaptations made in CDC's model. The phases of the adapted Kaizen as implemented by the CDC, including the high-level types of participants, are summarized in Figure 1.

Pre-Kaizen Planning

The pre-Kaizen planning is conducted within the sponsoring organization to understand and gain agreement on the scope of the work. For ACG, planning started 9 months ahead of the Kaizen event, beginning with leadership buy-in and a small planning committee at the sponsoring organization (CDC). This planning committee worked primarily on logistics, including security clearances for visitors to a federal facility, and policy items such as determining whether the Federal Advisory Committee

Act[27] applied since CDC is a federal agency. About 6 months before the Kaizen event, the initiative lead from the sponsoring organization with expertise in the process area of focus (ie, guideline development and implementation for ACG) and a Lean expert with experience in these types of events coordinated a 2-day in-person planning event, which took place 3 months in advance of the Kaizen (see Table 2 for a summary of steps in the Pre-Kaizen Planning Event).

During the first 1.5 days of the Pre-Kaizen Planning Event, a representative sample of subject matter and technical experts from different parts of the guideline development and implementation continuum came together from across CDC to define the problem statement and in- and out-of-scope items, determine

Table 2. Kaizen Process Steps Included in the Pre-Kaizen Planning Event.

| Kaizen process step	Pre-Kaizen planning event	
	Purpose	Technique
Problem scoping	1. Identify the problem and why it is important to solve. 2. Determine participants and key influencers who can affect change. 3. Determine what is in and out of scope based on what the Kaizen attendees have in their control to change. 4. Identify and recruit organizational leaders to support the work and participate in daily leader briefings	Use templates and mapping tools to assist in the scoping process.
Direct observation	Understand the current reality of the process to identify areas for improvement.	Observe individuals through simulation. Observers take detailed stepwise notes of what is happening.
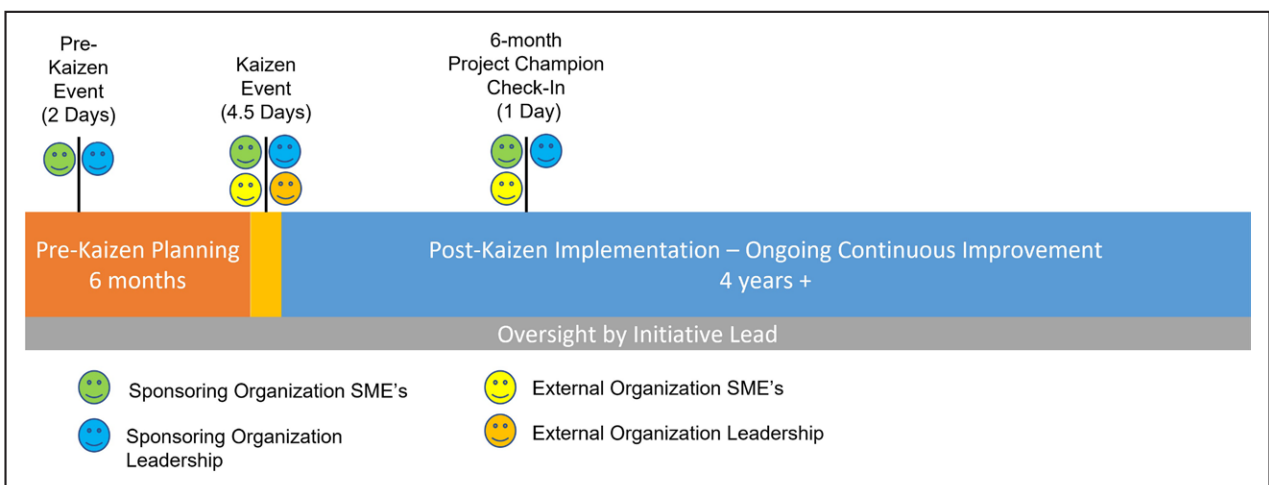
Figure 1. Phases of the adapted Kaizen as implemented for the Adapting Clinical Guidelines for the Digital Age initiative.

the types of expertise needed for the Kaizen event, and identify key leaders and influencers who are likely to affect change in the selected process. Once the high-level scope was established, the pre-Kaizen planning group determined the areas within that scope on which to focus as part of the ACG effort—5 key areas in total: (1) guideline creation, (2) informatics, (3) translation and implementation, (4) communication and dissemination, and (5) evaluation. Invited participants were subject matter experts (SMEs) or technical experts who regularly perform the work deemed in scope. The people who do the work are those who improve the work in the Lean methodology, therefore these SMEs and technical experts identified problems and solutions in each of the 5 focus areas. The invitees were selected based on (1) their roles in guideline creation, informatics, translation and implementation, communication and dissemination, or evaluation, and (2) relationships with CDC programs and experts involved in pre-Kaizen planning. The remaining half day of the pre-Kaizen planning event was focused on individuals from the sponsoring organization who volunteered to receive additional training to serve as facilitators for the breakout groups at the Kaizen event.

The pre-Kaizen planning group recognized that some of the experts needed for ACG had not likely worked together before (eg, guideline developers and informaticists) and identified a need to help them better understand each other's perspectives and terminology. CDC modified the adapted Kaizen method to resolve this issue in 2 ways. One way was by building information sessions into the Kaizen event that included representative presenters from each of the areas of expertise. The presentations would be optional and performed during the scheduled lunch hour, with 2 sets of speakers each providing half-hour presentations during the first 4 days of the Kaizen event. This portion of the event would be made available to a virtual audience to allow others not in attendance to learn as well. The other method was to include experts from each focus area in every workgroup (the Evaluation workgroup included evaluation experts and experts in guideline development, informatics, communication, and implementation, the Communication workgroup included communication experts and experts in guideline development, informatics, evaluation, and implementation, and so on). This was done to help ensure that upstream or downstream challenges from all perspectives could be discussed in each focus area.

Ideally, facilitators should be familiar with the Kaizen[23] process and have a background in Lean.[21] Since this was CDC's first Kaizen event, most of the facilitators were not familiar with Kaizen nor had a background in Lean. A subset of individuals from the pre-Kaizen planning group volunteered and were trained during the pre-Kaizen planning session to help lead each of the breakout groups during the Kaizen event. To augment the newly trained breakout group facilitators, experienced Kaizen facilitators (ie, the lead Kaizen facilitator, an additional co-facilitator, and the ACG lead) would circulate among the groups throughout the Kaizen event.

In addition to the above, pre-Kaizen planning included meeting logistics: large meeting room for full-group sessions (plenary, informational, report-outs), enough breakout rooms to support each breakout group, audiovisual support, web meeting setup for virtual participation, security clearances for on-site visitors (for federal or other secure facilities), check-in procedures, a list of nearby hotels for out-of-town participants, and lunch arrangements. Virtual participation in plenary sessions is another modification CDC added to the adapted Kaizen method. The virtual participation was not intended to replicate the in-person experience. Rather, it allowed individuals who were not able to attend in person to partially participate in the Kaizen event. It is worth noting that invited participants funded their own time and travel, including meals, for all stages of the event (ie, volunteered). Ensuring clarity about this up front was critical to maintaining the correct mix of participants.

Kaizen Event

CDC's Kaizen event included approximately 75 in-person participants and a range of 50–100 virtual participants in plenary sessions during the 4.5 days (see Table 3 for a summary of steps in the Kaizen Event). Each participant had expertise in one or more aspects of guideline development and implementation. The overall event was facilitated by 3 individuals with past experience with the CMS and ONC Kaizen efforts: (1) lead Kaizen facilitator—1 of 2 EIRs at HHS that helped CMS and ONC initially adapt Kaizen for eCQMs, (2) co-facilitator—participated in multiple CMS and ONC Kaizen events, and (3) ACG initiative lead—part of the group at CMS that led the initial set of US federal government Kaizen efforts to "Lean" the eCQM processes and participated in multiple CMS and ONC Kaizen events. Key CDC leaders (eg, Deputy Director for Public Health Science and Surveillance, various center directors) were also part of the event and made opening and closing remarks, listened to end-of-day report-outs, observed breakout groups, and asked questions. Leaders from participating organizations

Table 3. Kaizen Process Steps Included in the Kaizen Event.

	Kaizen event	
Kaizen process step	Purpose	Technique
Direct observation (continued from pre-Kaizen planning event)	Understand the current reality of the process to identify areas for improvement.	Observe individuals through simulation. The observers take notes of what is happening step by step.
Information sharing sessions (added step in adapted Kaizen)	Share knowledge from each perspective to help bridge knowledge and understanding gaps between different types of expertise represented at the Kaizen event.	Optional 30-minute plenary sessions, 2 each during the allotted lunch hour for each of the first 4 days of the Kaizen event.
Current state mapping	Create a visual representation of the way the current process is executed to reveal improvement areas.	Use data from the direct observations to map the high-level process flow steps, connections/people doing the work, and the detailed activities within the flow steps using standardized mapping conventions.
Ideal state	Determine what a perfect picture of the process would look like to strategically improve.	Brainstorm attributes to understand from the ultimate customer's perspective, the patient, what the ideal state would look like.
Waste identification	Identify areas throughout the process that are not adding value from the customer's perspective which are in the form of variation, transportation, inventory, motion, wait time, overproduction, overprocessing, or defects.	Mark waste on the current state map with a red dot. If waste is unclear, use the 5 whys root cause analysis tool to gain a deeper understanding.
Future state mapping	Create a visual representation of the first iteration of the future state process keeping the ideal state in mind to move strategically in that direction.	Identify waste to be removed within the implementation timeframe by using a green dot on the current state map. Create a new map depicting the future state process using standardized mapping templates.
Implementation planning	Define what is needed to successfully implement a standardized future state process.	Use templates to identify the following: documentation including workflows, standard operating procedures, and job aids, change management and testing requirements needed to ensure accuracy, training necessary for those impacted by the change, and identification of the project champion and team members to continue working on the project post the Kaizen event.
Watch-it metric creation	Determine what real-time metrics can be used to monitor the process to achieve the goals of the future state and avoid unintended consequences.	Use templates to walk through possible metrics to ensure real-time data for continuous improvement of the process.
Strong agreement	Ensure participants, including leadership, are in alignment on the proposed changes, goals, and resources needed to achieve the future state.	Participants divide into groups and discuss what challenges might be encountered and share their top 3. Leadership responds with a mitigation plan.
Reporting and communicating results	Facilitate decision-making, buy-in, and support for identified changes.	At the end of each day, each team reports out the progress to date and any learnings or "a-ha" moments. After each report-out, leadership and other interested parties ask questions and provide feedback.

not attending the in-person event could call in during full-group sessions and were encouraged to join during the end-of-day report-outs to hear about the progress made and "a-ha" moments. For CDC's ACG Kaizen, there was a broad representation of federal and state agencies, academia, nonprofits, and other private sector participants (Figure 2). Note that the "observer" category in Figure 2 represents virtual participants during the plenary and informational sessions.

Due to the large size of the Kaizen event in terms of both the number of participants and scope, the scope was broken down into several components (ie, sub-processes). For ACG, 5 areas served as breakout groups during the Kaizen event and later the workgroups for post-Kaizen implementation: (1) Guideline Creation, (2) Informatics, (3) Translation and Implementation, (4) Communication and Dissemination, and (5) Evaluation. As planned, each group included SMEs or technical experts with expertise in each of the focus areas, helping ensure well-rounded consideration from all relevant perspectives—a modification made by CDC to the adapted Kaizen method. The lead facilitator of the event, trained in Kaizen facilitation, instructed the audience in the steps of the Kaizen process. Rather than dedicate a block of time, in the beginning, to explain the entirety of the Kaizen process, the lead facilitator broke down the information throughout the event by each step. The pattern included a plenary session describing one of the steps, groups breaking out and applying that step, groups reconvening and reporting the results of each step, learning about the next step from the lead facilitator, and repeating the in-group work and report-outs. Breakout group facilitators—identified and trained at the pre-Kaizen planning session—shepherded each respective group through each step. The lead Kaizen facilitator, co-facilitator, and ACG initiative lead circulated among the breakout groups to help answer questions and keep the process moving. A final report-out to leadership—those attending in person and leaders from
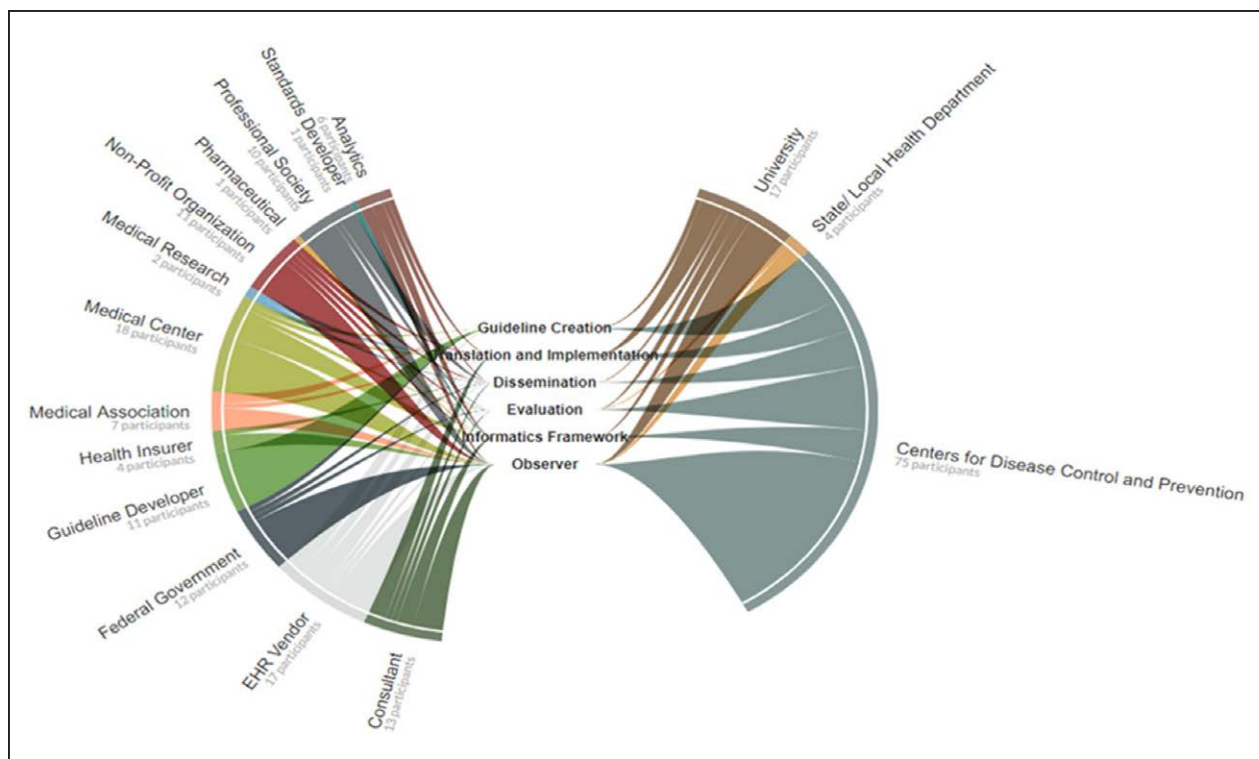
Figure 2. Participant mix for Centers for Disease Control and Prevention's Kaizen event by organization type and breakout group (figure courtesy of Linda Roesch).

participants' organizations that joined virtually—summarized each of the steps for each group, with emphasis during the final report-out on the future state and implementation planning.

Figures 3A–3C show photos of the CDC Kaizen event process used in February 2018. The mapping follows a systematic color-coded method. Each Post-It color represents a different layer of the process: blue for flow steps (top level); green for the connection or person doing the work (middle level); orange for the activities performed by the connection for each flow step (bottom level); and purple for waiting time (wherever identified within the mapped process). The red dot stickers represent items identified as waste in the current state, and the green dot stickers represent waste that is being removed in the future state.

Post-Kaizen Implementation

Post-Kaizen implementation constitutes the bulk of the work of any Kaizen effort and continues to apply Lean/Agile principles and practices. For ACG, the workgroups each developed and iterated on products as they learned from their end users to help operationalize the proposed future state for each of the 5 focus areas. This included weekly virtual meetings of each workgroup, ongoing project planning, using tools to track the work progress (eg, Kanban boards, other project management tools), and reviewing the status of "watch-it" indicators which provided metrics used to gauge whether the changes were resulting in achieving the intended outcomes as well as identify areas for continuous improvement on the future state. Each of the workgroup leads, also called project champions, leveraged expertise in each of the 5 areas to determine the best approach and what products were needed for their portion of the overall scope. For ACG, each workgroup developed interrelated products to support the future state.[8,28–31]

Monthly project champion virtual meetings were held to update the ACG initiative lead on progress against objectives and to share experiences among groups, offering help to each other when needed. In addition to the project champions, ACG participants could also attend these meetings, another change from the CMS and ONC Kaizens. This served several purposes: to keep the broader ACG community apprised of progress across the workgroups, allow input from the broader community, and help participants learn from others in the community about successes, challenges, prioritizations, etc. related to applying the ACG work in their respective

Figure 3. Vignettes from the Adapting Clinical Guidelines for the Digital Age Kaizen event. A, The breakout group performs current state mapping of the translation and implementation process. B, Current state map shows waste identified to remove in the future state for the informatics group. C, A group presents current and future state plans to ensure alignment across the groups ("report-out").

Figure 3. Continued.

organizations. At a 6-month post-Kaizen check-in event, the workgroup leads reconvened in person to gauge progress, reflect on watch-it indicators, and plan for the next 6 months. This process is typically repeated until full implementation of the future state has been achieved, however, only one 6-month in-person check-in occurred with the ACG Kaizen.

Results

The outcome of the ACG Kaizen event is summarized in Figure 4. The Kaizen participants identified 4 primary root causes of lag time in getting evidence-based guidelines into patient care: (1) unnecessarily redundant translations of the recommendations (eg, from published guidelines to CDS then from CDS to patient care workflows in each individual health care organization applying the guideline), (2) issues experienced downstream in the process that resulted from upstream activities (eg, vague language in the written guideline recommendation making it difficult to translate to a computer interpretable tool such as CDS), (3) lack of a standard way to consistently translate written recommendations into computer interpretable representations, and (4) a lack of consistent feedback loops within the continuum of guideline development and implementation. In the proposed future state, all the perspectives would be part of the process from the outset, with co-developed written and computable guidelines and upfront planning for communication and evaluation. This new approach would eliminate most of the unnecessary redundancies, provide a way for the downstream perspectives to identify the issues as they happen during the upstream activities so they could be corrected or improved before they could cause issues later in the process, develop a standard way to consistently translate written recommendations into computer interpretable representations (ie, computable guidelines), and provide a framework for evaluation that could help close incomplete feedback loops. These aspects of the proposed future state for the ACG initiative were facilitated by the adapted Kaizen method, which included multiple disciplines and multiple organizations involved in guideline development and implementation. The products developed by each of the workgroups during post-Kaizen implementation incorporated standards, processes, and tools to help achieve the proposed future state and are described in detail in separate publications.[8,27–31]

As with most approaches, there were enablers and challenges with applying and further adapting the Kaizen method for the ACG initiative. Workgroups that had leads who were familiar with Lean,[21]
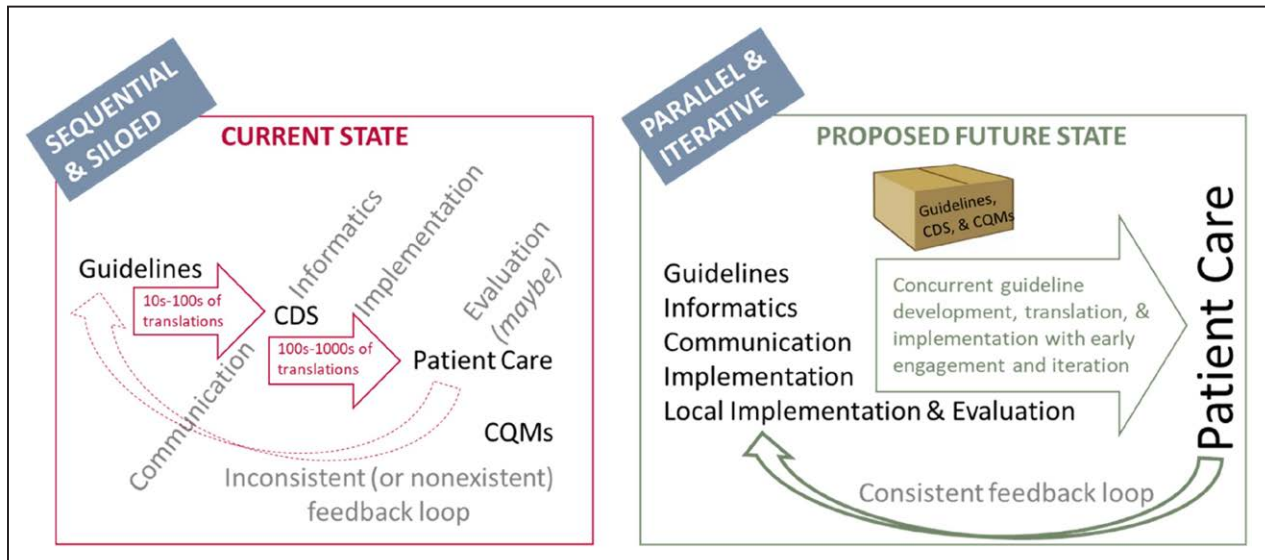
Figure 4. Adapting Clinical Guidelines for the Digital Age Kaizen event outcome: pictorial summary of the current state and proposed future state.[30]

Agile,[32,33] human-centered design,[34,35] or similar methods seemed to acclimate more easily than groups that lacked this familiarity (eg, informatics experts often use Agile development methods for their work while guideline developers, at least at the time of the Kaizen event, did not generally use Agile techniques). Logistic enablers included adequate space, facilities, supplies, technology, connectivity, and necessary roles (eg, facilitation, project champions willing to apply the Kaizen method). Logistics were also needed for the post-event work, including document-sharing space, web meeting links, and call details that participants could access (ie, central workspace, accessible communication method). Regular virtual meetings of each workgroup (usually weekly) and project champions (usually monthly) helped ensure the workgroups continued to progress and could communicate with other workgroups. A 6-month post-Kaizen in-person check-in with the project champions of each workgroup, the ACG initiative lead, and the lead facilitator gave everyone a chance to regroup and review progress and challenges, exchange ideas across workgroups, and allow for deeper discussion.

Each workgroup's products were determined by the group with the guidance of the leads. For example, the Guideline Creation Workgroup determined that developing an iterative and integrated process for guideline development and implementation, building on best practices, and redesigned to include products and suggestions from the other workgroups would help develop a more cohesive proposed future state.[28] The Informatics Workgroup determined that developing a health information technology (IT) standard for developing computable representations of clinical practice guidelines, with modular, reusable components that facilitate implementation in patient care, was best suited to accomplish their portion of the overall scope (ie, Fast Healthcare Interoperability Resources [FHIR®] Clinical Guidelines, or CPG-on-FHIR®).[30] The Implementation Workgroup developed checklists that became part of the Informatics workgroup's health IT standard.[31] The Communications and Dissemination Workgroup identified or developed a variety of tools that became part of the Guideline Creation Workgroup's integrated process.[28] The Evaluation Workgroup developed a way to systematically evaluate the integrated process and its products and outcomes as it is being implemented.[29] While each workgroup developed separate products, the adapted Kaizen method enabled collaboration, which resulted in the interrelatedness of the collective ACG products described in more detail in a separate article.[8]

In terms of challenges, since the event's scope was broad and some participant groups were interacting for the first time, the extra time and effort needed to help the groups better understand each other's perspectives and terminology was necessary but significantly slowed the overall effort. Despite a mix of expertise in each workgroup, some participants chose to change groups on their own. Everyone who did this switched from a group whose scope was not in their primary area of expertise to a group that was. This resulted in some groups having less of the

expertise represented by those individuals, at least during the Kaizen event, though every group had at least 1 individual from each perspective throughout the Kaizen and post-Kaizen activities. Additionally, the adapted Kaizen method provided an opportunity for each workgroup to access expertise in other groups (eg, report-outs during the Kaizen event, and project champion meetings during post-Kaizen implementation), which mitigated the effects of the individuals who switched groups. Most but not all Kaizen event participants continued their participation through the creation of their respective workgroup's primary product. For those participants who did not continue, most cited competing priorities or a change in organization or role as the primary reason for their attrition. Conversely, other individuals became interested in the initiative and joined after the Kaizen event. The applicable expertise of the new participants balanced with the needs for certain expertise in each workgroup helped determine to which workgroup each new participant would be assigned. Some participants also chose to contribute to multiple workgroups, which further assisted in sharing expertise and experiences between the workgroups. New participants heard about the initiative through webinars, conference presentations, workshops, and existing ACG initiative participants. Most new participants met with the ACG lead to learn about the context of the initiative, provide information about their perspective within guideline development and implementation, and express their specific interest in the initiative and in a particular workgroup(s). Before assigning a new participant to a workgroup, the ACG lead conferred with the project champions, providing the new participants' perspective and interest, and working together to ensure a good fit. A few participants immediately joined a specific workgroup because an existing member of that group identified each of their expertise as helpful to that particular workgroup. Overall, many more participants joined the ACG initiative than left it.

Most of the work in any Kaizen effort is performed after the event. The time and effort needed from project champions to serve as workgroup leads throughout the post-event period was sometimes too great without sufficient administrative support. For most participants, Kaizen was a new concept. The focus on developing a future state with major improvements rather than incremental changes of the current state was a different way of planning, which resulted initially in some variability in the application of Kaizen. The combination of limited administrative support and the novelty of the approach led to varied pace of completion of activities. For the adapted Kaizen approach to succeed, enough participants must be willing to try the Kaizen process (like the change adoption curve,[36] in which some individuals are early adopters of new technology). By design, each workgroup determines what products should be developed to achieve the future state outlined for their group's scope during the Kaizen event. Not all workgroups completed their products at the same pace. This appeared to be correlated with the leads' everyday work, though a formal analysis was not performed. For example, the Informatics and Implementation workgroup leads that use similar methods (eg, Agile) to develop or implement health IT tools began developing their products during or soon after the Kaizen event. Other workgroup leads felt the Kaizen process had "failed." Their stated reasons included their inability to determine as quickly what products they needed to support their respective future state or the assumption that this should have been determined during the 4.5-day Kaizen event. The mixing of expertise within workgroups and the 6-month in-person check-in with the workgroup leads provided well-rounded feedback to incorporate into their respective products.

One of the biggest and unforeseen challenges was the COVID-19 pandemic, which slowed or paused most of the work of the ACG initiative for almost 3 years. However, it also presented a unique opportunity to apply multiple ACG initiative products that were in development in an informal pilot. In May 2020, a group of ACG initiative participants joined with professionals from nearly 50 private sector organizations (eg, hospitals and health systems, medical specialty societies, and IT vendors) to form the COVID-19 Digital Guideline Working Group (C19 DGWG). Details of the work of the C19 DGWG are described in CPG-on-FHIR®,[30] the integrated process article,[28] and the evaluation framework article.[29] The C19 DGWG partnered with the American College of Emergency Physicians to produce guidance for its 50,000 members within 3 months, including computable guideline products based on the draft CPG-on-FHIR® standard and applying aspects of the integrated process and evaluation framework, such as including all perspectives from the beginning. This example demonstrates the type of impact and reaches that the Adapted Kaizen method can have (eg, reducing the time for development and dissemination of written and computable guidance to 3 months, a few ACG participants connected with many other health and informatics professionals and helped apply the proposed future state of ACG).

The CDC's ACG products and concepts have already been used by multiple programs, partners,

and other efforts. For example, several CDC programs have used and helped inform CPG-on-FHIR®. Guideline examples include opioid prescribing (National Center for Injury Prevention and Control),[37] anthrax (National Center Emerging and Zoonotic Infectious Diseases),[38] alcohol screening and brief intervention (National Center for Birth Defects and Developmental Disabilities),[39–41] gestational diabetes and contraception and cervical cancer screening and management[42] (both from the National Center for Chronic Disease Prevention and Health Promotion), and HIV screening (National Center for HIV, viral Hepatitis, STD, and TB Prevention). Note, the computable guidelines on gestational diabetes and contraception, cervical cancer screening and management, and HIV screening are in progress and have not yet been published. Non-CDC partners have also used CPG-on-FHIR® for developing computable guidelines (eg, National Heart Lung Blood Institute with asthma guidelines,[43] C19 DGWG in partnership with the American College of Emergency Physicians with guidance on risk stratification for patients with COVID-19 in the emergency department, and the World Health Organization with antenatal care guidelines).[44] The World Health Organization has also begun a parallel effort similar to ACG called Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable Guidelines.[45,46] Participants in the ACG and Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable Guidelines initiatives frequently work together and learn from each other, with the initial connection between the groups being made by one of the ACG Kaizen participants. Additionally, private companies have adopted the FHIR®-based standards incorporated into CPG-on-FHIR® to build clinical practice guideline tools for deployment within EHRs and health systems.[47]

Other groups incorporated ACG standards, processes, and tools into their own tools and recommendations. For example, federal partners at the Agency for Healthcare Research and Quality used parts of CPG-on-FHIR® in their CDS Connect platform.[48,49] One way was applying metadata for the computable guideline products published on the CDS Connect repository based on CPG-on-FHIR®. Another way was developing the CDS authoring tool to produce code following the approach and methodology described in CPG-on-FHIR®. The President's Cancer Panel recommended computable guidelines and CDS for all cancer screening guidelines and specifically recommended using CPG-on-FHIR® as the data and exchange standard.[50] The American Society of Clinical Oncology released a request for information on

piloting its own computable guidelines projects and using CPG-on-FHIR® (Hans Messersmith, email communication, May 9, 2022). The ACG initiative has also been included in a textbook for introductory health informatics courses for health sciences students, the health informatics community, computer science and IT professionals interested in learning about the field, and practicing health care providers.[51]

Discussion

Industries outside of health care and public health have led the way in innovative process reengineering and design.[9,10] However, the health sector has much to gain from these approaches due to the vast complexity, cost, and top-down managerial approach. The US federal government shares many of these challenges and could take the lead in encouraging the health industry to move rapidly toward modernization. Using approaches like Lean, Agile, and human-centered design could help leap forward toward a cultural change that empowers patients and health care workers to streamline policies and procedures; reorient the work toward quality and safety; incorporate more efficient and effective feedback loops; and bring patients back to the center of focus while gaining value through the reduction of documentation, administrative, and process waste. This article describes how a Kaizen activity can help accelerate a holistic and human-centered focus on guideline development and implementation to reduce the lag time between evidence generation and implementation of guidelines into practice.

The ultimate gains will require a significant shift in the culture of health care, public health, and federal work to be realized. By creating an ever-enlarging pool of process improvement champions, leaders can foster and spread the success of these techniques across organizations until the culture change permeates all aspects of work. Key to this kind of success is the participation and support of leaders, who themselves embrace the new approach to work and seek to eliminate roadblocks that hamper improvement.

The experience from CDC's ACG Kaizen effort identified the need for dedicated planning time and resources, adequate facilitation and space for the activities, and appropriate follow-up infrastructure for communication, knowledge management, administrative support, and a set of clear objectives. A key need is ongoing resources to support the work after the event, as this is the time when the future state is implemented and maintained. An annual cycle for the adapted Kaizen approach for complex systems may be necessary when several cycles of improvement are needed to get close to the future state. This approach can be

combined with Agile project management[52] on a daily, weekly, or monthly basis to ensure the investment in continuous improvement is a regular part of the work. Additional modifications could be made to the adapted Kaizen method to further expand virtual participation in the Kaizen event. A fully virtual Kaizen event will likely present additional challenges such as less opportunity for networking and serendipitous moments of discovery between participants, technical limitations of participants, or technical problems with the technologies used. However, a completely virtual approach may also create additional benefits, especially logistical considerations such as eliminating the need for a large amount of physical space to be reserved for 4.5 days, for travel to a specific location, and for organizations such as US federal agencies, the need for security clearances for visitors.

Conclusion

Adapting Kaizen from its traditional use in business to streamline large, complex processes that health-related federal agencies are involved in has been a multiagency effort over the past decade. The adaptations have included ways to incorporate the perspectives of multiple disciplines with individuals from many organizations (public and private sector) contributing to the holistic understanding and redesigning of large, complex processes. While there were some challenges with coordination, participation from the various disciplines and organizations is also what made a holistic approach possible to help identify the root causes of the challenges in the current siloed nature of guideline development and implementation. The CDC's ACG initiative shows the effectiveness of the adapted Kaizen method because using such an approach is what facilitated the types of interdisciplinary products developed and interactions required for broad awareness and use, unlike more siloed approaches. Long-term investment in these techniques has the potential to create cultural change toward an innovation and experience-centered approach that will yield both immediate and long-term effectiveness and efficiency.

Conflicts of Interest

The authors have no conflicts of interest to disclose.

Disclaimer

The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Department of Health and Human Services.

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